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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,011	09/05/2003	Ann M. Maloney	10/041-2-C2	1738
28510	7590	09/10/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P O BOX 368 RIDGEFIELD, CT 06877				FUBARA, BLESSING M
ART UNIT		PAPER NUMBER		
		1615		

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/657,011	MALONEY, ANN M.
	Examiner Blessing M. Fubara	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 05 September 2003.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 44-49 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 44-49 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. 10/085,597.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>08/09/2004</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment and application data sheet filed 09/05/03 and IDS filed 08/09/04. Claims 44-49 are pending.

### *Priority*

Applicant's claim to subject matter disclosed in prior Application No. 10/085,597, filed 02/27/2002 and a claim to subject matter disclosed in Application Nos. 09/626,584 filed 07/27/2000 and 60/146,298 filed 07/29/1999 is acknowledged. The reference to prior application has been made in the application data sheet.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 appears to limit composition 44 by having hydroxypropylcellulose, hydroxypropylmethyl cellulose and hydroxyethylcellulose. However, claim 44 requires that matrix forming polymer be either alkylcellulose or hydroxyalkyl cellulose. It also appears that claim 45 intended to recite that the C1-C6 hydroxyalkylcellulose is selected from the group consisting of hydroxypropylcellulose, hydroxypropylmethyl cellulose and hydroxyethylcellulose. Claim 45 is examined as such and support for this interpretation is found in the disclosure at page 12, lines 7 to the end from the bottom.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 44 and 46-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Eichman (US 5,980,882).

Eichman discloses a solid dosage form comprising narcotic analgesic drug (oxycodone, codeine, hydrocodone, dihydrocodeine), ion exchange resin (divinylbenzene sulfonic acid cation exchange resin, AMBERLITE IRP-69 or AMBERLITE-IRP 70) and alkyl cellulose polymer. Examples 2 and 3 teach a composition comprising carboxymethylcellulose and ethylcellulose respectively. In example 2, ethylcellulose is about 3.4%. The cationic exchange resins used in Eichman have particle sizes ranging from about 25  $\mu\text{m}$  to about 1000  $\mu\text{m}$  (column 6, line 65 to column 7, line 5). The composition of Eichman further comprises a chelating agent. Eichman teaches that the ion-exchange resin can be any non-toxic ion-exchange resin, cation exchange or anion-exchange and the drug can be basic, acidic or amphoteric. See abstract, column 3, line 28 to column 7 line 21, column 8, lines 25-34, column 13, lines 9-13, examples 2 and 3 and claims 1-3.

Amount of the matrix polymer in Eichman is encompassed in the recited amount of from about 1-20% and a point within recited range coincides with the amount in Eichman. Similarly,

the particle size of the resin recited in the claims is encompassed in the disclosed particle size of the prior art and a particle size of 50  $\mu\text{m}$  is anticipated by a particle size in the Eichman particle size range of 2  $\mu\text{m}$  to 1,000  $\mu\text{m}$ . Ethylcellulose is an alkylcellulose. Amberlite IR-120 and IR-70 are divinylbenzene sulfonic acid cationic ion exchange resin (column 7, lines 3-6). Also, Eichman discloses suitable resins as resins derived from divinylbenzenes, trivinylbenzenes, styrenic, methacrylic, methacrylamide and polyhydroxy resins and inorganic and amphoteric and zwitterionic resins (column 6, lines 42-64). Eichman meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eichman (US 5,980,882) in view of Chow et al. (US 4,160,827).

Eichman clearly discloses the instant solid dosage form. Eichman does not disclose hydroxyalkylcelluloses.

Chow discloses a composition comprising sulfonic acid cationic exchange (AMBERLITE IRP-70) resin, pharmaceutically active basic drugs selected from dextromethorphan, codeine, hydrocodone, morphine and propanolol) and an effective amount of hydroxypropylmethyl cellulose, hydroxypropyl cellulose and polyvinylpyrrolidone for a

prolonged continuous release of the active drugs. Chow further teaches that the hydroxyalkyl celluloses are in amounts ranging from about 3% to about 20% and the polyvinylpyrrolidone are in amounts ranging from about 7% to 20%. See column 1, lines 36-58 and column 2, lines 12-63. The particle size of the resin is from about 25  $\mu\text{m}$  to about 1000  $\mu\text{m}$  (column 2, lines 53-57).

From about 3% to about 20% polymer of Chow meets the limitation of 1-20% polymer recited in the instant claims, and specifically, example 1 of Chow teaches 13% hydroxypropyl cellulose. 25  $\mu\text{m}$  to about 1000  $\mu\text{m}$  sized particles read on particles sized at 50  $\mu\text{m}$ .

Since Eichman discloses solid dosage form comprising hydrocodone, ion exchange resin (divinylbenzene sulfonic acid cation exchange resin, AMBERLITE IRP-69 or AMBERLITE-IRP 70) and alkyl cellulose polymer; and Chow discloses a composition comprising sulfonic acid cationic exchange (AMBERLITE IRP-70) resin, pharmaceutically active basic drugs selected from dextromethorphan, codeine, hydrocodone, morphine and propanolol) and an effective amount of hydroxypropylmethyl cellulose; and both Eichman and Chow use equivalent ion exchange resins in formulations that contain hydrocodone; and the difference in the matrix of Chow and Eichman is that Eichman uses ethylcellulose and Chow uses hydroxypropylcellulose or hydroxypropylmethyl cellulose; it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of Eichman. One having ordinary skill in the art would have been motivated to substitute one cellulose polymer for another, and specifically substitute the cellulose polymer of Chow for the ethylcellulose with the expectation of success in forming hydrocodone-resin or oxycodone-resin complexes.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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